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**POLICY AND PROCEDURES**

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**OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY****Use of Review Templates in the Office of Surveillance and Epidemiology**

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**PURPOSE**

This MAPP establishes policies and procedures for using standardized templates for documenting reviews in the Office of Surveillance and Epidemiology (OSE) in the Center for Drug Evaluation and Research (CDER). OSE review templates are intended to assist OSE reviewers in creating organized, clear and concise review documents. Further, the routine use of OSE templates will enable the readers of OSE reviews to more readily access the information needed to conduct CDER's regulatory work.

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**POLICY**

1. The OSE review templates available on the CDER/OSE Intranet Web site will be used to document OSE review work.
2. The OSE Intranet templates Web site will include the latest version of each review template.
3. Reviewers will select the OSE template that is most relevant to their discipline and/or review type. Team leaders will assist with template selection, if needed.
4. Signoff authorities in OSE (e.g., team leaders, division directors, and office directors) will ensure that appropriate OSE templates are used for documentation of OSE review work.
5. The assessment of data and conclusions of the reviewer in the review cannot be altered after the review is finalized (and archived in the appropriate administrative record). Following the finalization (and archiving) of the review, any changes or additions to assessments or conclusions must be documented in a subsequent (addendum) review and archived separately.

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6. Instructions on the use of OSE templates (Attachment 1), OSE division-specific review writing guides, and conventions of the CDER *Reviewer Style Manual* will be followed when completing OSE reviews.
  7. Additional reviewer instructions, such as detailed reviewer guides and discipline best-practice documents, are optional and will be consistent with (and will not conflict with) the guidelines outlined in this MAPP.
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## RESPONSIBILITIES

- The **reviewer will** complete each designated review using the appropriate review template from the CDER/OSE Intranet Web site. Reviewers should engage in scientific and regulatory dialogue with team leaders, supervisors, and others to develop complete and scientifically valid review perspectives. However, the final conclusions and recommendations in the review should reflect the OSE reviewer's own opinion.
  - The **team leader will** promote consistent use of the appropriate review template by reviewers. Team leaders should engage OSE reviewers in scientific and regulatory exchanges regarding reviews before finalization of the review. When the reviewer's conclusions and/or recommendations differ from those of the team leader, team leaders should encourage reviewers to document their own conclusions and recommendations in the review. If the team leader is the signatory authority for the OSE review, the team leader is expected to write his or her own memorandum, noting the reasons for any differences in recommendations from those of the reviewer.
  - **Division and office management** will promote consistent use of the review templates and provide scientific and regulatory perspective on review issues. For example, when the reviewer's conclusions and/or recommendations differ from those of the division director (or office director), the division director (or office director) should encourage the reviewer to document the reviewer's own conclusions and recommendations in the review. The division director (or office director) is expected to write his or her own memorandum, noting the reasons for any differences in conclusions and recommendations from those of the reviewer (see CDER MAPP 4151.1, "Scientific/Regulatory Dispute Resolution for Individuals Within a Management Chain").
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## PROCEDURES

1. OSE reviewers will select the review template from the OSE Intranet site that is most relevant to the type of OSE review being written. Reviewers should select a fresh template from the OSE Intranet site each time a new review is written, to ensure use of the latest version of the review template.

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2. OSE reviewers should follow the advice provided in Attachment 1 regarding ordering of headings, use of subheadings, and content of main review headings.
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## REFERENCES

1. MAPP 4151.1, "Scientific/Regulatory Dispute Resolution for Individuals Within a Management Chain"  
<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM289019.pdf>
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## DEFINITIONS

- **OSE Review:** An OSE review documents the review methods, analyses, assessments, conclusions, and recommendations of OSE review staff in any of the OSE divisions or offices.
  - **OSE Review Template:** A structured outline for the preparation of OSE reviews. Templates are specific to the type of review and/or the review discipline in one or more OSE divisions. The OSE review templates outline the organization of content, promote review documentation consistency, and provide for ready retrieval of information.
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## EFFECTIVE DATE

This MAPP is effective upon date of publication.

**ATTACHMENT 1****Advice on Use of OSE Templates****Most OSE Reviews Are Written Using the Scientific Format**

OSE reviews involving analyses of data and assessment of results will generally be written in the format that is typical for scientific papers (i.e., abstract, introduction, methods, results, discussion) and will contain specified main headings in the order below. Other formats, such as those used to review sponsor submissions, are acceptable as specified in each OSE-approved template.

The Table of Contents may be omitted if the review is fewer than five pages (not counting cover page or attachments) in length. References and Appendices will only be included if relevant.

COVER PAGE  
TABLE OF CONTENTS  
EXECUTIVE SUMMARY  
INTRODUCTION  
BACKGROUND  
METHODS AND MATERIALS  
RESULTS  
DISCUSSION  
CONCLUSION  
RECOMMENDATIONS  
REFERENCES  
APPENDICES

**When To Include, Omit, or Add Subheadings**

Each OSE review template will contain subheadings under its specified main headings that are relevant to the type of review (e.g., drug use analysis, adverse event report analysis, or risk evaluation and mitigation strategy (REMS)). Reviewers may add additional subheadings when completing a review to address data or topics not included in the template. Subheadings may be deleted when the subheading is not relevant to the data to be included in a particular review. Reviewers are encouraged to confer with their team leader when making decisions on what subheadings to add to or delete from a particular review.

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**Advice on Content of Main Headings**

**EXECUTIVE SUMMARY**

- The Executive Summary should only include the most important information from the review. The Executive Summary should include a purpose statement, overall conclusions, key reasons for the overall conclusions, and the general recommendations.
- Begin the Executive Summary with a purpose statement. It is recommended that the purpose statement from the Introduction be used. If needed, add a sentence or two expanding on the topic or reason for the request.
- Limit the length of the Executive Summary to no more than one page.
- It is recommended that the reviewer create the Executive Summary as the last step in completing the review, to enable easy extraction of key information and messages from the other sections of the review.

**INTRODUCTION**

- The Introduction consists of a main “Introduction” heading and up to three subheadings (“Background,” “Regulatory History,” and “Product Labeling”) as relevant to the review.
- Under the main “Introduction” heading, include a brief, but specific statement explaining the reason for the review, such as receipt of a consultation, an OSE-generated safety signal, or response to a citizen petition.
- Information in the subheadings should be kept as brief as possible, including only information relevant to the review.

**Background**

- Include the drug name, its indication(s) for use and any other relevant information about the drug (only as pertinent to the review). Explain the event(s) that led to the review as well as any other pertinent background to provide context for the reader.
- Include mention of previous OSE reviews only if relevant to the current review; if mentioned, include the list of previous OSE reviews in the References section.

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## Regulatory History

- State the approval date of the drug and other regulatory history since approval (only as relevant to provide context for the review). Do not include every regulatory action, labeling supplement submission, or labeling change, that has occurred since approval.

## Product Labeling

- Include only the sections of labeling that are relevant to the review. If the review necessitates inclusion of large portions of (or the entire) labeling, include the labeling information as an appendix.

## METHODS AND MATERIALS

- Briefly discuss the material or data sources reviewed and the methods (analytic methods or other) used to review the material. If databases are used, put detailed descriptions or limitations in the appendices, rather than in the body of the review.
- Do not include results in the Materials and Methods section.

## RESULTS

- Include factual results without interpretation relevant to the review's purpose.
- Avoid inclusion of extraneous information that will not be used in your assessment
- Key tables and figures, if helpful to convey important information, can be placed in the Results section of the review. Extensive presentation of results, such as multi-page tables, should generally be avoided unless needed for understanding of the review; if important for the review, they should be included in appendices.

## DISCUSSION

- Begin each paragraph with a finding (objective) or opinion (subjective), followed by factual data to support it. Using information from Results, include key findings and the rationale that led to the overall conclusions, supporting the assessment or opinion with relevant facts, as needed. The discussion section should address any data included in the Results section (see drug use example under Results). Explain how the conclusion suggests the need for the recommendations. Explain how the reader should interpret the results, and any other factors that could explain the results. Describe limitations of the data, if relevant. Do not introduce results that were not in the Results section.

## CONCLUSION

- State your conclusion briefly to summarize the overall findings (e.g., *Based on the AERS data and information from Study A, the use of drug X appears to be associated with adverse event Y; the proposed REMS submission for Drug X from Sponsor Y is acceptable.*)
- The rationale for your conclusion should be placed in the Discussion section.
- Recommendations should not appear in the Conclusion section; place recommendations in the separate Recommendations section.

## RECOMMENDATIONS

- A bulleted (or numbered) format is preferred for recommendations. Recommendations are preferably placed in “rank order” of importance.
- Recommendations that are intended to be communicated to the sponsor need to be “letter ready” by wording the recommendations in such a way that can be copied from the OSE review and pasted (by an OSE, Office of New Drugs [OND] or other CDER office Regulatory Project Manager [RPM]) into a letter to the sponsor. A subheading such as “Comments to the Sponsor” will clearly communicate which recommendations are intended for the sponsor. Recommendations directed to others, such as an OND division, should also be given a similar subheading (such as “Comments to the OND Division”).
- Detailed rationale used for formulating recommendations should be placed in the Discussion section of the review so that the Recommendations section can be concise and the recommendations are easy for the reader to locate.